UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW HAMPSHIRE

Cheryl Lees

v. Civil No. 10-cv-084-JD
Opinion No. 2011 DNH 039

Harvard Pilgrim Health Care
of New England

O R D E R

Cheryl Lees brought suit under the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1132(a)(1)(B), to require Harvard Pilgrim Health Care of New England ("HPHC") to cover the cost of permanent implantation of a "peripheral nerve stimulator (occipital neuromodulation treatment)," which was prescribed to treat Lees's headaches.[1] Lees argues that she is entitled to coverage for the treatment under the terms of the Plan. HPHC contends that it correctly determined that the treatment was not covered under the Plan, because it is excluded as a procedure that is "Experimental, Unproven, or Investigational."

[1]Lees was a participant in the Harvard Pilgrim Best Buy HMO New Hampshire Benefit Plan ("Plan"), provided through her husband's employer.

Background

The parties provided a joint statement of material facts, and each provided a statement of disputed facts. Lees includes facts taken from materials provided to HPHC after the coverage decision was made. HPHC challenges Lees's reliance on the new materials.

"The decision to which judicial review is addressed is the final ERISA administrative decision." Orndorf v. Paul Revere Life Ins. Co., 404 F.3d 510, 519 (1st Cir. 2005). Absent unusual circumstances, substantive evidence that was not included in the administrative record cannot be considered on review. Id.; Urso v. Prudential Ins. Co. of Am., 532 F. Supp. 2d 292, 302 (D.N.H. 2008); McGillivray v. Life Ins. Co. of N. Am., 519 F. Supp. 2d 157, 167 (D. Mass. 2007). As Lees provides no reason why the extra-record evidence should be considered, the court will not consider evidence, designated "AR Supp.," that was not included in the administrative record.

Lees suffered from "intractable daily migraine headaches" for years and tried many treatments without success. Lees's pain management specialist, Dr. Joshua Greenspan, recommended implantation of a peripheral nerve stimulator for occipital neuromodulation treatment, occipital neurostimulation. A

temporary trial of the stimulator was required before permanent implantation could be done.

HPHC provided coverage for the temporary trial based on the billing codes entered by Lees's physician. HPHC contends that the codes provided were incorrect, which caused coverage to be allowed erroneously. The temporary trial implantation occurred in July of 2008 and was successful. Lees found that her pain was relieved by 95% and that she was able to sleep. Lees's surgeon, Dr. Philip R. Anderson, then requested coverage from HPHC for a permanent implantation. Permanent implantation would have been an out-patient procedure.

On July 30, 2008, HPHC denied coverage for permanent implantation of the peripheral nerve stimulator. In denying coverage, HPHC stated that "peripheral nerve stimulation is not a covered benefit for treating cervical cranial syndrome under [Lees's] HPHC-NE plant. HPHC-NE considers this procedure unproven at this time, as there is insufficient evidence in the published peer review literature supporting the long-term effectiveness and safety of this procedure." Lees appealed the decision and included letters from her physicians and her psychologist in support of her appeal. On October 7, 2008, HPHC's Member Appeals Committee voted to uphold the decision denying coverage.

Lees requested reconsideration, which was reviewed by the Member Appeals Reconsideration Committee. The Reconsideration Committee affirmed the earlier decision on December 3, 2008. Lees then sought an external review by the New Hampshire Insurance Department, and on February 12, 2009, the review organization upheld the decision to deny coverage. Lees then filed suit in this court.

Discussion

Lees contends that she is entitled to coverage from HPHC for permanent implantation of the peripheral nerve stimulator. HPHC argues that the decision to deny coverage was correctly made under the terms of the Plan. The parties agree that the de novo standard applies.

Under the de novo standard, the court "independently weigh[s] the facts and opinions in the administrative record to determine whether the claimant has met [her] burden of showing that [she] is [entitled to coverage] within the meaning of the [Plan]." Richards v. Hewlett-Packard Corp., 592 F.3d 232, 239 (1st Cir. 2010). Therefore, the court gives no deference to the administrative decision. Orndorf, 404 F.3d at 518. In contrast, when the Plan grants discretionary authority to the Plan Administrator, "a reviewing court must uphold that decision

unless it is arbitrary, capricious, or an abuse of discretion." Cusson v. Liberty Life Assurance Co. of Boston, 592 F.3d 215, 224 (1st Cir. 2010).

The Plan states that the basic requirements for coverage are that the medical service or supply must be medically necessary, a covered benefit, not excluded, received while covered by the Plan, provided by or on referral from the participant's primary care physician, and provided by an HPHC-NE provider. AR 107. Among the exclusions are "[a]ny products or services, including, but not limited to, drugs, devices, treatments, procedures, and diagnostic tests that are Experimental, Unproven, or Investigational." AR 121. HPHC determined that the exclusion for experimental, unproven, or investigational procedures applied to occipital neurostimulation, precluding coverage for implantation of the nerve stimulator in Lees's case.

A. Experimental, Unproven, or Investigational

HPHC denied coverage under the exclusion for experimental, unproven, or investigational procedures because "there is insufficient evidence in the published peer review literature supporting the long-term effectiveness and safety of this procedure." Joint Facts ¶ 6. The Plan defines "Experimental, Unproven, or Investigational" as products, services, treatments,

and procedures that are "not recognized in accordance with generally accepted medical standards as being safe and effective for the use in the evaluation or treatment of the condition in question." AR 147. To determine whether a procedure is generally recognized as safe and effective, "primary reliance will be placed upon data from published reports in authoritative medical or scientific publications that are subject to established peer review by qualified medical or scientific experts prior to publication." Id. If such reports are not provided, "it will generally be determined that a service, procedure, device or drug is not safe and effective for the use in question." Id.

Lees argues that she proved that occipital neurostimulation treatment was not experimental, unproven, or investigational.[2] Lees states that her experience with the trial implantation demonstrated that the treatment was a success, that her medical care providers recommended the procedure, that her medical providers gave opinions about the treatment based on their experiences with other patients, that published reports submitted

[2]Lees also provides several arguments to show that the administrative decision was arbitrary and capricious. That is not the correct standard, however. Instead, Lees bears the burden of showing that she is entitled to coverage under the terms of the Plan.

for consideration supported the procedure, and that occipital neurostimulation is covered by other health care benefit providers. HPHC responds that it correctly determined that occipital neurostimulation is excluded from coverage because it is experimental, unproven, or investigational.[3]

Lees's individual experience with the occipital neurostimulation treatment and the opinions of her treating physicians do not show that the treatment has been shown by generally accepted medical standards to be safe and effective. Therefore, that information does not counter the application of the exclusion for experimental, unproven, or investigational procedures.

The published reports that Lees cites in the administrative record to show that the treatment is not experimental, unproven, or investigational do not accomplish that purpose. Lees merely cites the reports in their entirety without any analysis of specific parts of the reports that might support her position. In the absence of an appropriate evaluation of the published reports for purposes of Lees's case, their evidentiary value is

[3]HPHC refers to the procedure as "occipital neurostimulation," while Lees refers to a "peripheral nerve stimulator" and "occipital neuromodulation treatment." Although the parties do not address the different terminology, they appear to be referring to the same treatment or procedure.

limited in this context. Further, on their face, the reports do not support Lees's argument that the treatment has been recognized by generally accepted medical standards as being safe and effective. Instead, the medical reports document preliminary positive results with small groups, suggest that the treatment could be a useful tool in certain cases, and note that further controlled studies are necessary.

HPHC explains that it does not evaluate new procedures and technology in individual cases. Instead, as provided in the Plan, HPHC staff, working in teams, evaluate new technologies by researching the safety and effectiveness of the technology in an "evidence-based evaluation process." AR 144. The team reviews medical reports and literature, consults with expert practitioners, and considers how other insurers and public agencies treat the new technology. Based on its review, the team arrives at a policy recommendation that it presents to an internal policy committee charged with making decisions about coverage for new technology.

An evaluation was completed for occipital neurostimulation for treatment of intractable headaches that resulted in a medical policy statement, dated September of 2008. The policy provides the supporting information, including an assessment of the technology, a literature review, and a summary the policies of

other insurers and agencies. The conclusion, "Policy and Coverage Criteria," is stated as follows: "HPHC does NOT cover occipital nerve stimulation for intractable headache. It is considered experimental and unproven."

Lees argues that certain bits and pieces of the information provided in the occipital neurostimulation policy statement support her position that the treatment is safe and effective. She also faults HPHC for failing to cite the policy statement in considering her appeals. Lees's arguments are not persuasive.

To the extent Lees contends that the research reported in the occipital neurostimulation policy statement supports coverage, she failed to show that to be true. Because the policy statement found that occipital neurostimulation is experimental and unproven, whether or not the HPHC's appeal committees cited the statement is not material to Lees's argument here. Therefore, Lees has not carried her burden of showing that the cited exception for experimental, unproven, or investigational procedures does not apply to occipital neurostimulation.

B. Medically Necessary

Lees also argues that the nerve stimulator was medically necessary in her case. Because the exclusion for experimental, unproven, or investigational procedures applies, it is not

necessary to address her argument on whether the procedure was medically necessary.

Conclusion

For the foregoing reasons, the plaintiff's motion for judgment (document no. 19) is denied. The defendant's motion for judgment (document no. 22) is granted.

The clerk of court shall enter judgment in favor of the defendant and close the case.

SO ORDERED.

Joseph A. DiClerico, Jr.
United States District Judge

March 16, 2011

cc: Janine Gawryl, Esquire
John-Mark Turner, Esquire